ICU
MANAGEMENT & PRACTICE

Bayer's Xarelto® Approved in the EU for Secondary Prevention after an Acute Coronary Syndrome

Following an ACS event, one in ten patients will have another major atherothrombotic event (cardiovascular death, myocardial infarction or stroke) within a year / Xarelto 2.5 mg BID in combination with antiplatelet therapy can help prevent athero-thrombotic events by providing more complete protection than antiplatelet therapy alone / Xarelto is approved to protect patients from blood clots across more venous and arterial thromboembolic conditions than any other novel oral anticoagulant

Bayer HealthCare's novel oral anticoagulant Xarelto® (rivaroxaban) has been approved by the European Commission for the prevention of atherothrombotic events (cardiovascular death, myocardial infarction or stroke) after an Acute Coronary Syndrome (ACS) in adult patients with elevated cardiac biomarkers at a dose of 2.5 mg twice-daily (BID) in combination with standard antiplatelet therapy. This approval makes rivaroxaban the only novel oral anticoagulant approved to protect patients with elevated cardiac biomarkers following an ACS event.

Arterial blood clots, which may lead to a recurrence after an ACS event, are formed through the dual pathways of platelet activation and thrombin generation. Standard antiplatelet therapy only targets the platelet activation pathway of clot formation. Rivaroxaban targets Factor Xa, a key trigger of thrombin generation.

"We know that thrombin levels remain elevated long after an ACS event, leaving patients at risk. In the ATLAS ACS 2-TIMI 51 study, we've shown that treating these patients with a low dose of rivaroxaban in combination with standard antiplatelet therapy targets both pathways of clot formation providing more complete long-term protection, including significant reduction in mortality risk," said C. Michael Gibson, M.S., M.D., Chairman of the PERFUSE Study Group, Harvard Medical School, and the Principal Investigator in the ATLAS ACS studies. "This approval marks an important shift in the way we deliver protection to patients who are at risk of a secondary atherothrombotic event."

"Xarelto is already finding extensive use by cardiologists for stroke prevention in patients with atrial fibrillation. This approval re-enforces the compelling profile of the product, further extending its clinical value in preventing arterial blood clots," said Dr. Kemal Malik, Member of the Bayer HealthCare Executive Committee and Head of Global Development.

The approval of rivaroxaban in this indication is based on important clinical findings of the pivotal Phase III ATLAS ACS 2-TIMI 51 study of more than 15,500 patients. The study demonstrated that the addition of rivaroxaban 2.5 mg BID to standard antiplatelet therapy — low-dose aspirin with or without a thienopyridine (clopidogrel or ticlopidine) — significantly reduced the composite primary efficacy endpoint of cardiovascular death, myocardial infarction or stroke in patients after a recent ACS compared to those who received standard antiplatelet therapy alone.

Rates of TIMI (**T**hrombolysis **I**n **M**yocardial **I**nfarction) major bleeding events not associated with coronary artery bypass graft (CABG) surgery and of intracranial haemorrhage (ICH) were low overall, yet increased with the addition of rivaroxaban. But importantly, there was no increase observed with rivaroxaban in the risk of fatal intracranial haemorrhage (ICH) or fatal bleeding.

Based on the ATLAS ACS 2-TIMI 51 study findings, the 2012 European Society of Cardiology (ESC) Guidelines recommend that treatment with rivaroxaban 2.5 mg BID be considered for patients with ST-Segment Elevation Myocardial Infarction (STEMI) who are at low bleeding risk and are on antiplatelet therapy with aspirin and clopidogrel.

Source: Bayer AG

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